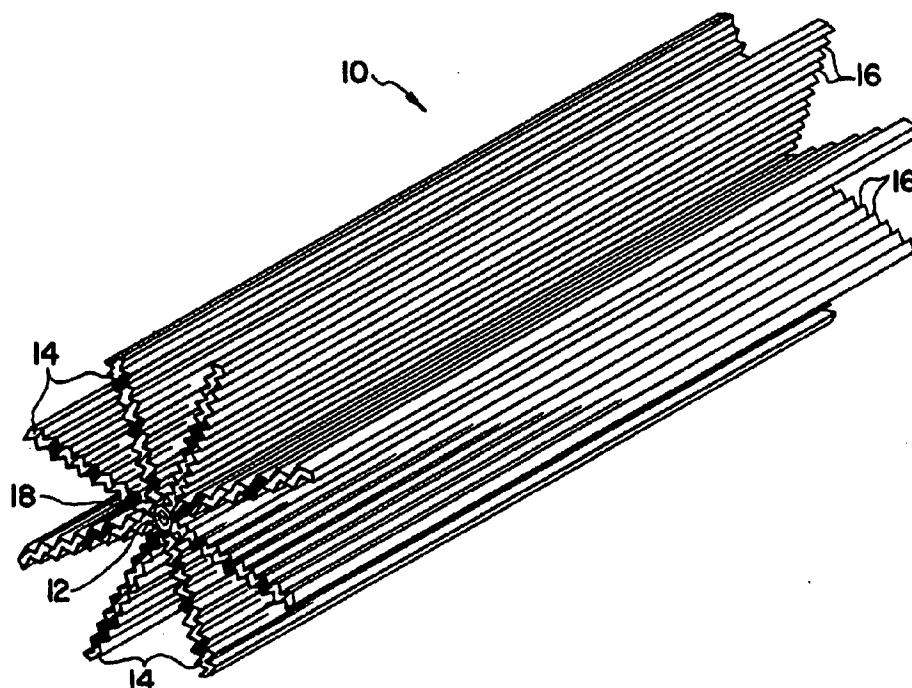




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(54) Title: WINGED BILIARY STENT



(57) Abstract

A stent (10), for example, for maintaining the patency of a duct such as a biliary duct, is provided that includes a plurality of radially extending wings (14). The wings (14) project from a core (18) which has guide wire or wire stylet lumen. Each of the wings (14) preferably include a plurality of minute, longitudinally extending grooves (16) for bile flow even in the event of tumor ingrowth. The core itself is preformed into a helical configuration.

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WINGED BILIARY STENTBACKGROUND OF THE INVENTION1. Field of the Invention

5 The present invention relates to a stent that can be used to maintain flow in ducts in the body and, more particularly, to a stent for biliary drainage in patients whose biliary channels are obstructed for example due to cancer or benign disease.

10 2. Description of the Related Art

 There are at least 4,000 new cases of biliary cancer, and more than 25,000 cases of pancreatic cancer every year, and the incidence appears to be rising. These cancer present with
15 jaundice, due to obstruction of the bile duct. Unfortunately, by the time this stage is reached the tumor is usually at an advanced stage and unresurrectable. Management at this stage, therefore, usually consists of palliation only.

20 Although surgical bypass procedures are effective for palliative purposes, most patients with these cancers are either too sick to undergo major surgery or have too short a life-span to make the operation worthwhile. For this reason,
25 palliation of jaundice in these biliary cancers is most often done by the endoscopic insertion of a biliary stent or endoprosthesis across the obstructed area. These are of two types: 1)
30 plastic, and 2) expandable metal stents. Both types of conventional stents have problems associated with their use. Conventional plastic stents tend to clog with debris and biofilm relatively early. Metal stents overcome this problem by providing a greater initial lumen but also tend to clog, in their case

with tumor ingrowth. Also, metal stents are extremely expensive, about 20 times more expensive than plastic stents. Even further, the metal stents are technically more difficult to insert and once in
5 place, can not be removed.

SUMMARY OF THE INVENTION

The present inventors have overcome the foregoing problems and have invented a stent that uses flow along surfaces and not flow within a
10 center lumen to maintain fluid flow in biliary ducts or any other duct in a body.

Thus, it is an object of the present invention to provide a stent which combines the many advantages of a plastic stent while avoiding the
15 problems with biofilm build-up and stent obstruction. A stent according to the proposed invention does not require luminal flow through an obstructed center lumen, as in prior art devices. Instead, the invention relies on flow along a
20 plurality of surfaces.

The foregoing and other objects are realized in accordance with the present invention by providing a stent comprising an elongated main body or core member having a guide wire or wire stylet
25 and a plurality of wing elements extending outwardly from the core member. The wing elements may be uniformly distributed about the circumference of the core member. Each wing has a length at least about as great as a length of the core member and a width
30 that is preferably substantially greater than a cross-sectional dimension of the core member. If a guideline or wire stylet is used to place the stent, the core member may have a small lumen defined centrally for placement of the guideline.

35 In accordance with the presently preferred embodiment, there are a plurality of wing elements

and each wing has a plurality of grooves defined on each surface thereof for laminar fluid flow therealong. Further, the core itself may be helically twisted.

5 Other objects, features, and characteristics of the present invention as well as the methods of operation and functions of the related elements of the structure, and the combination of parts and economies of manufacture, 10 will become more apparent upon consideration of the following detailed description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate 15 corresponding parts in the various figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an enlarged schematic, partial perspective view of a stent provided in accordance with the invention; and

20 FIGURE 2 is a view similar to FIGURE 1, but of an alternative stent configuration in accordance with the invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EXEMPLARY EMBODIMENTS

25 In accordance with the present invention, a stent 10 is provided that includes an elongated core or main body 12 and a plurality of wings or fins 14 which extend generally radially from the 30 core 12. In the illustrated embodiment, eight uniformly distributed fins 14 are provided. It is to be appreciated, however, that fewer or more fins may be found to be advantageous, depending upon the body passage or duct into which the stent 10 is 35 adapted to be placed and the disposition of the fins 14 on the core 12.

In the illustrated embodiment, the wings or fins 14 each extend substantially continuously along the entire length of the core or main body 12. Furthermore, each fin or wing 14 is parallel to and extends longitudinally of the core 12. It is to be appreciated, however, that the invention is not necessarily limited to the illustrated configuration. The only requirement is that there are a plurality of surfaces that encourage flow along those surfaces.

In accordance with the most preferred embodiment, each of the wings 14 is grooved or corrugated on each side and/or the wings 14 are undulated, to define numerous small grooves 16 on each side for providing a capillary flow effect along the length thereof. The core 12' of the stent 10' may itself be twisted in a helical fashion or the wings 14' otherwise formed to describe a helix, as illustrated in FIGURE 2.

There is no lumen as such through the core of the stent. Instead, a guide wire or wire stylet lumen 18 only is provided. Flow along the body passage in which the stent 10 is disposed, such as the bile duct, is therefore along the capillary like grooves 16 on the surfaces of the wings 14 and intermediate the wings 14. The grooves 16 provide more surface area, and, the greater the surface area the more fluid tension pulling fluid along. Thus, grooves 16 along the winged surface enhance flow by providing capillary like flow. Thus, by eliminating a large central lumen for flow, the turbulence in flow that inevitably results in biofilm formation has also been avoided. The foregoing was a major problem with conventional plastic stents.

The stent core 12 and wings 14 are preferably integrally formed from a plastic material such as polyethylene coated with a hydrophilic

substance such as Hydromer so as to further reduce biofilm build-up. Tumor ingrowth is not expected to impair the function of the herein disclosed stent because the unique configuration of the stent will require that, to fully block flow, the tumor must physically grow into each of the channels 16, in each of the wings 14. Such ingrowth is extremely unlikely to occur during the expected lifetime of the patient. Other substances may also be incorporated into the surface coating the stent such as antibiotics (to inhibit bacterial growth), tumoricidal drugs or agents or other therapeutic substance.

The stent of the invention can be inserted endoscopically, percutaneously or surgically. Specifically, a guide wire (not shown) is first threaded through the obstructing lesion and beyond. Thereafter, the stent is threaded over the guide wire through stylet lumen 18. The stent is then pushed through the obstructing lesion with a pusher tube (not shown) which is placed in surrounding relation to the guide wire as well, in the usual fashion. The pusher tube and guide wire are then removed.

While the invention as been disclosed in particular with reference to bile duct obstruction, it is to be appreciated that the stent of the invention may useful in the event of pancreatic lesions or indeed a variety of ductal obstructions in other sites of the body such as in the urethra, fallopian tubes or other body passages.

Although not illustrated in particular, in certain environments it may be desirable to provide a retaining structure at each longitudinal end of the stent to resist movement in the duct in which it is disposed.

While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but on the contrary is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

WHAT IS CLAIMED IS:

1. A stent comprising:
an elongated main body member having first and second longitudinal ends and a longitudinal axis extending therebetween;
a plurality of wing elements extending outwardly from said main body member, said wing elements being substantially uniformly distributed about an outer circumference of said main body member, each said wing element having a length at least about as great as a length of said main body member and a width substantially greater than a cross-sectional dimension of said main body member, wherein each said wing element has a plurality of longitudinally extending grooves defined on each side face thereof.
2. A stent as in claim 7, wherein each said wing element extends radially outwardly from said main body member.
3. A stent as in claim 7, wherein said main body member has a stylet lumen defined axially therethrough, coincident with said longitudinal axis, for placement of a guide wire.
4. A stent as in claim 7, wherein there are at least four wing elements.
5. A stent as in claim 10, wherein there are eight wing elements.
6. A stent comprising an elongated main body member having first and second longitudinal ends and a longitudinal axis extending therebetween;
a plurality of wing elements extending outwardly from said main body member, said wing

elements being substantially uniformly distributed about an outer circumference of said main body member, each said wing element having a length at least about as great as a length of said main body member and a width substantially greater than a cross-sectional dimension of said main body member, wherein each said wing element has first and second longitudinal side faces, at least one of said longitudinal side faces having a plurality of grooves defined therein and extending longitudinally thereof.

7. A stent as in claim 7, wherein said wing elements are preformed to extend in a helical configuration along said main body member.

8. A stent as in claim 7, wherein said main body member is formed from polyethylene.

9. A stent as in claim 7, wherein said wing elements are coated with a hydrophilic substance.

10. A stent as in claim 7, wherein said wing elements are coated with a therapeutic substance.

11. A stent as in claim 7, wherein said wing elements are integrally formed with said main body member.

12. A stent as in claim 13, wherein each said wing element extends radially outwardly from said main body member.

13. A stent as in claim 13, wherein said main body member has a stilet lumen defined axially

therethrough, coincident with said longitudinal axis, for placement of a guide wire.

14. A stent as in claim 13, wherein there are at least four wing elements.

15. A stent as in claim 13, wherein said wing elements are preformed to extend in a helical configuration along said main body member.

16. A stent as in claim 13, wherein said wing elements are coated with a hydrophilic substance.

17. A stent as in claim 13, wherein said wing elements are coated with a therapeutic substance.

18. A stent comprising:
an elongated main body member having first and second longitudinal ends and a longitudinal axis extending therebetween;
a plurality of wing elements projecting outwardly from said main body member, said wing elements being substantially uniformly distributed about an outer circumference of said main body member, each said wing element extending in a helical configuration along said main body member so as to have a length greater than the length of said main body member, each said wing member having first and second longitudinal side faces along which fluid flows due to the action of surface tension provided by such surfaces.

19. A stent as in claim 25, when at least one of said longitudinal side faces has a plurality

of grooves defined therein and extending longitudinally thereof.

20. The stent of claim 25, wherein said longitudinal side surfaces are coated with a hydrophilic substance.

21. The stent of claim 25, wherein said longitudinal side surfaces are coated with a therapeutic substance.

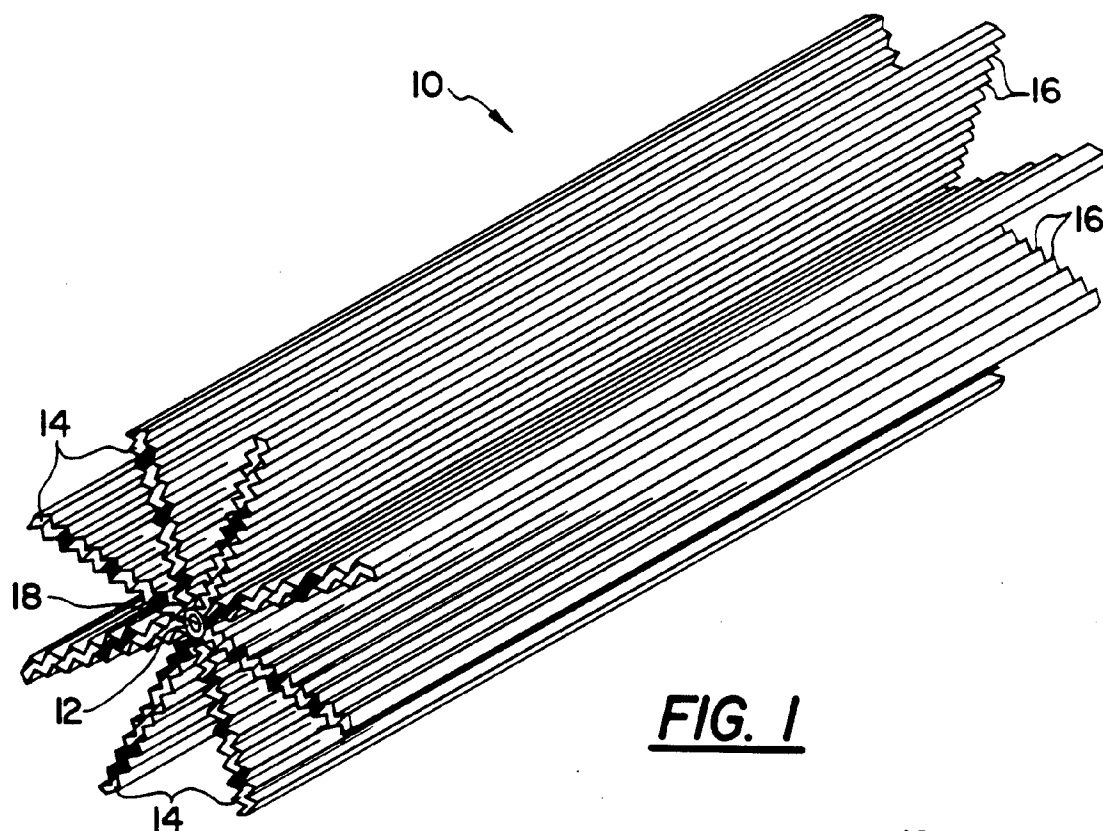


FIG. 1

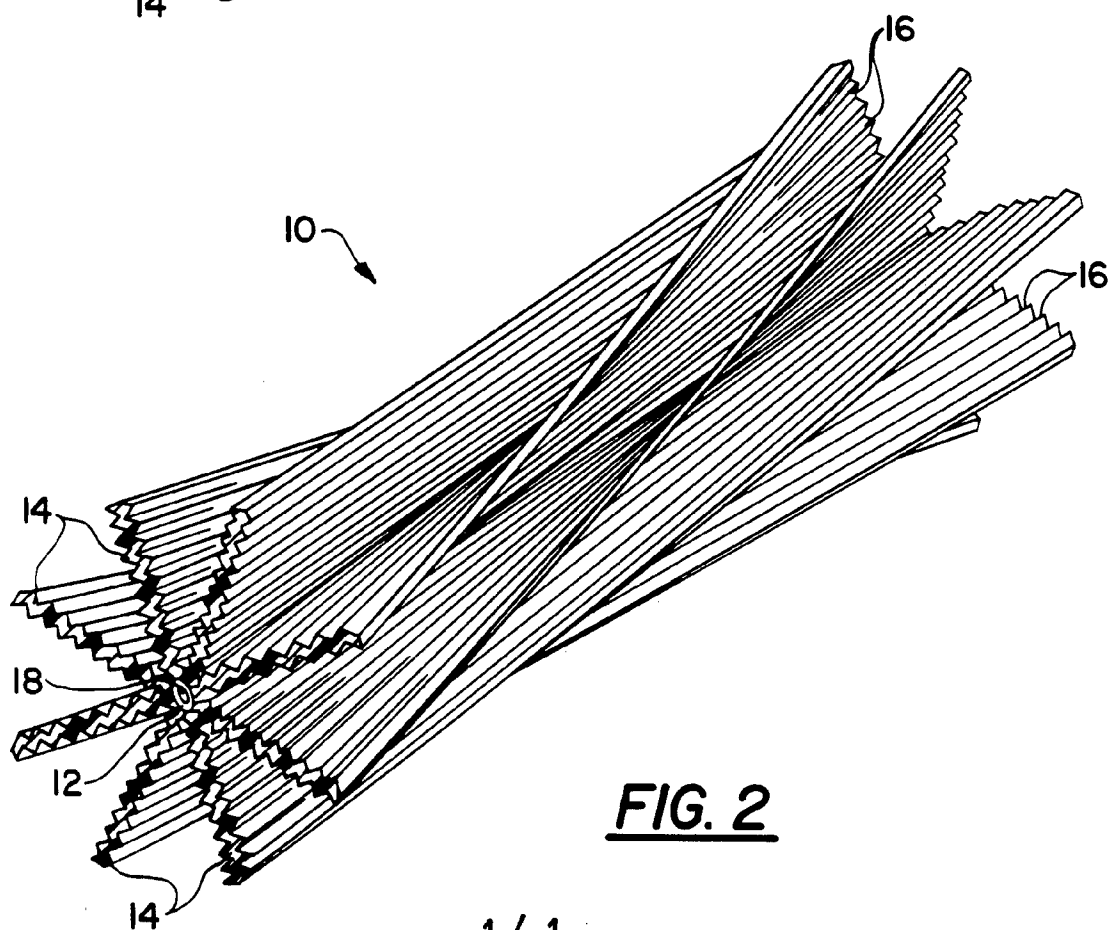


FIG. 2

INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/US95/00970

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 5/00, 27/00

US CL : 128/897; 606/191

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897-899; 604/8, 264; 606/1, 191, 198, 200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 3,821,956 (GORDHAMER) 02 July 1974. See whole document.	1-21
Y	US, A, 4,459,318 (HYANS) 10 July 1984. See whole document.	20
Y	US, A, 4,677,143 (LAURIN ET AL.) 30 June 1987. See whole document.	21
Y	US, A, 4,795,439 (GUEST) 03 January 1989. See whole document.	18, 20, 21
Y	SU, A, 1641-356 (KUIB CITY HOSPITAL) 15 April 1991. See figures, and abstract.	18, 20, 21
A	GB, A, 189,127 (HANTCHER) 03 May 1923. See whole document.	1-21

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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Date of the actual completion of the international search 28 MARCH 1995	Date of mailing of the international search report 21 APR 1995
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